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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/717,294	09/20/96	SEED B	007867345001

CLARK & ELBING
176 FEDERAL STREET
BOSTON MA 02110-2214

19M1/0817

EXAMINER
DEGEN, N

ART UNIT	PAPER NUMBER
1941	13

DATE MAILED: 08/17/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/717,294

Applicant(s)
Seed et al.

Examiner
Nancy J. Degen

Group Art Unit
1941



☒ Responsive to communication(s) filed on May 26, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-28 is/are pending in the application.

Of the above, claim(s) 11-16 and 21-24 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-10, 17-20, and 25-28 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6, 8, 12

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Sequence Information

1. The Sequence Listing filed November 17, 1997 has been approved.

Election/Restriction

2. Applicant's election without traverse of claims 1-10, 17-20 and 25-28 in Paper No. 11 is acknowledged.
3. Claims 11-16 and 21-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected species. Election was made **without** traverse in Paper No. 11.

Oath/Declaration

4. The petition filed January 16, 1997 has been granted. The declaration is accepted without the signature of inventor Jurgen Haas.

Drawings

5. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.
6. The drawings are considered to be informal because they fail to comply with 37 CFR 1.84(a)(1) which requires black and white drawings using India ink or its equivalent.

Photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(1) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings,

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a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(I), three sets of drawings or photographs, as appropriate, and, if filed under the provisions of 37 CFR 1.84(a)(2), an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-10, 17-20 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 1, lines 5-6, the phrase "being capable of expressing" implies a latent ability which may or may not function as claimed. It is suggested that "being capable of" be deleted.

At claim 2, line 2, the phrase "is capable of expressing" implies a latent ability which may or may not function as claimed. It is suggested that "is capable of expressing" be changed to

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--expresses--.

At claim 3, line 2, the phrase "being capable of expressing" implies a latent ability which may or may not function as claimed. It is suggested that "is capable of expressing" be changed to --expresses--.

At claim 4, line 2, the phrase "being capable of expressing" implies a latent ability which may or may not function as claimed. It is suggested that "is capable of expressing" be changed to --expresses--.

At claim 18, lines 1-2, there is no clear antecedent basis for the phrase "said human protein". It is believed that this claim should depend from claim 17 instead of claim 1.

At claim 27, line 1, the phrase "harboring with" is unclear. It is suggested that --which harbors-- be used instead.

At claim 28, line 7, --so that a synthetic gene is prepared-- should be inserted after "codon".

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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10. Claims 1-10, 17-19 and 25-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Seed et al. (World Patent Application No. 96/09378).

Seed discloses synthetic genes encoding mammalian proteins that are expressed at a higher level than native genes. The synthetic genes have non-preferred codons replaced by preferred codons. Proteins such as Factor VIII may have their expression level increased by replacing codons. Expression levels can be increased by as much as 10,000%. From 10%-90% of the codons in the natural protein are non-preferred and/or are replaced. Vectors containing the synthetic gene and mammalian cells harboring the vector are also disclosed (Seed, page 1, line 20 through page 4, line 26). Seed also teaches that in a preferred embodiment the CG sequence is highly under represented (Seed, page 17, lines 27-39 and page 25, line 22 through page 26, line 34). Seed discloses each and every aspect of the instant invention, thereby anticipating Applicants' claimed invention.

11. Claims 1-10, 17-19 and 35-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Seed et al. (U. S. Patent No. 5,786,464).

Seed discloses synthetic genes encoding mammalian proteins that are expressed at a higher level than native genes. The synthetic genes have non-preferred codons replaced by preferred codons. Proteins such as Factor VIII may have their expression level increased by replacing codons. Expression levels can be increased by as much as 10,000%. From 10%-90% of the codons in the natural protein are non-preferred and/or are replaced. Vectors containing the synthetic gene and mammalian cells harboring the vector are also disclosed (Seed, col. 1, line 29

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through col. 2, line 63). Seed also teaches that in a preferred embodiment the CG sequence is highly under represented (Seed, col. 10, line 58 through col. 11, line 3 and col. 14, line 57 through col. 15, line 33). Seed discloses each and every aspect of the instant invention, thereby anticipating Applicants' claimed invention.

12. Any inquiry concerning this communication or earlier communications from the Adjudicator should be directed to Nancy J. Degen, whose telephone number is (703) 306-3492. The Adjudicator can normally be reached on Monday-Thursday from 8:00 AM-5:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Adjudicator by telephone are unsuccessful, the Adjudicator's supervisor, Angela Sykes, can be reached at (703) 306-3484 and the Patent Analyst, Michelle Mosley can be reached at (703) 306-3494. The fax phone number for this Group is (703) 308-4363.

Any inquiry of a general nature or relating to the status of this application should be directed to the Patent Assistant, Marianne Morgan, whose telephone number is (703) 306-3475.

MM
MM
NJD
August 17, 1998



**NANCY DEGEN
PRIMARY EXAMINER**